

AUG 10 1998

FREEDOM OF INFORMATION SUMMARY

Supplement to NADA 140-974

IVOMEC[®] (ivermectin) Premix for Swine

“...for the treatment and control of threadworms(*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets via the colostrum or milk, when fed during gestation)”

Sponsored by:

MERIAL LIMITED

Date Approved:

I. GENERAL INFORMATION

NADA Number: 140-974

Sponsor: Merial Limited
2100 Ronson Road
Iselin, New Jersey 08830-3077

Established Name: ivermectin

Trade Name: IVOMEC® Premix for Swine

Marketing Status: over-the-counter (OTC)

Effect of supplement: New claim for the treatment and control of threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets via the colostrum or milk, when fed during gestation) and use of Type C medicated feed as a top dress for adult swine.

II. INDICATIONS FOR USE

For the treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrongylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae), kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae), lungworms (*Metastrongylus* spp., adults), lice (*Haematopinus suis*), and mange mites (*Sarcoptes scabiei* var *suis*). Additional indications contained in this supplemental NADA are for treatment and control of threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation).

III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND DOSAGE

- A. Dosage Form: Type A medicated article to be mixed with feed to produce a Type B or C medicated feed.
- B. Route of Administration: Orally, through feed
- C. Approved Dose: 0.1 mg ivermectin/kg (2.2 lb) of body weight daily for 7 consecutive days.

IV. EFFECTIVENESS

Data demonstrating the effectiveness of IVOME[®]C Premix for Swine for previously approved indications are discussed in FOI Summaries for NADA 140-974 dated September 23, 1993 (58 FR 58652; Nov. 3, 1993), and June 29, 1995 (60 FR 39847; Aug. 4, 1995). Data from the following dose confirmation trials demonstrate that IVOME[®]C Premix for Swine given at the recommended dosage controls infections of adult *Strongyloides ransomi* and prevents transmission of infective *S. ransomi* larvae from sows to piglets, via the colostrum or milk, when IVOME[®]C Premix is given in the feed during gestation.

A. Confirmation of effectiveness of ivermectin in swine feed for threadworms (*S. ransomi*)

Note: Percent effectiveness was calculated using the formula: $[(\text{Arithmetic mean number of nematodes in non-medicated swine}) - (\text{Arithmetic mean number of nematodes in ivermectin-treated swine})] \div [(\text{Arithmetic mean number of nematodes in non-medicated swine}) \times 100] = \text{Percent Efficacy}$.

Trial ASR 14712 and Trial ASR 14774

1. Type and purpose of study: Induced infection in pregnant sows to determine the effect of ivermectin treatment during gestation on transcolostral transmission of larvae.
2. Investigator: Marlene Drag, D.V.M.
Merck & Co., Inc.
Fulton, Missouri
James Arends, M.S., Ph.D.
2340 Sanders Road
Willow Spring, NC 27592
3. General design:
 - a. Animals: Twenty-four (24) crossbred sows (8 per group) each had at least one previous litter and were bred over a known three-day interval.
 - b. Induced infection: Infective larvae of *S. ransomi* were given by subcutaneous injection to each animal on three occasions during the interval from Days 63 to 80 (ASR 14712) or Day 57 to 78 (ASR 14774) of gestation. On each occasion approximately 250,000 larvae were given.
 - c. Dosage form and dose of test articles: Type C medicated feed fed to deliver 100 mcg ivermectin/kg body weight/day for seven consecutive days. One group received ivermectin from Days 0 to 7 and the other group received it from Days 11 to 18, with Day 0 being the 92nd day of gestation. Control animals received feed containing vehicle of the IVOME[®]C Premix for Swine on Days 0 to 7.
 - d. Test duration: For each sow, until 14 days after parturition.
 - e. Pertinent variables measured: Worm counts for up to 4 piglets per sow at 14 days of age; and larval counts in sow colostrum or milk at 1, 2 and 7 days after parturition.

4. Results: Trial results are summarized in Tables 4.1 and 4.2.

Table 4.1. Mean worm counts and percent worm reduction at 14 days of age in up to 4 piglets/sow from 8 sows fed either control ration or ration containing 100 mcg ivermectin/kg body weight/day for seven consecutive days

Treatment Group	Adult <i>S. ransomi</i> ^a	Percent reduction
Trial ASR ASR 14712		
Vehicle Control	3274.4	-
IVOMEC Premix (Days 92 to 99)	0	100
IVOMEC Premix (Days 103 to 110)	0	100
Trial ASR ASR 14774		
Vehicle Control	828.1	-
IVOMEC Premix (Days 92 to 99) ^b	0	100
IVOMEC Premix (Days 103 to 110)	0	100

^aArithmetic mean

^bSome sows were treated from Day 93 to 100 of gestation.

Table 4.2. *S. ransomi* larval counts in colostrum or milk at 1, 2, and 7 days after parturition from sows fed either control ration or ration containing 100 mcg ivermectin/kg body weight/day for seven consecutive days

Treatment Group	Day of Sample					
	Day 1		Day 2		Day 7	
	Number larvae	Percent reduction	Number larvae	Percent reduction	Number larvae	Percent reduction
Trial ASR ASR 14712						
Vehicle Control	117.0	-	10.0	-	5.2	-
IVOMEC Premix (Days 92 to 99)	0	100	0.1	98.8	0	100
IVOMEC Premix (Days 103 to 110)	0	100	0	100	0	100
Trial ASR ASR 14774						
Vehicle Control	83.0	-	35.5	-	0	-
IVOMEC Premix (Days 92 to 99) ^b	0	100	0	100	0	-
IVOMEC Premix (Days 103 to 110)	0	100	0	100	0	-

5. Conclusion: Under the conditions of this study, IVOMEC® Premix for Swine prevented transmission of *S. ransomi* larvae from sows to piglets, *via* the colostrum or milk, when given in the feed of sows during gestation.
6. Adverse reactions: No adverse events related to treatments were observed.

Trials ASR 14775 and ASR 14820

1. Type of study: Induced infections of *S. ransomi* to determine the efficacy of treatment against patent infections of *S. ransomi* in growing pigs.
2. Investigator: James Arends, M.S., Ph.D. Bruce Kunkle, D.V.M., M.S.,
2340 Sanders Road Ph.D.
Willow Spring, NC 27592 Merck & Co., Inc.
Fulton, Missouri
3. General design:
 - a. Animals: In each trial there were twenty female and male-castrate crossbred pigs (10 per group). Trial-ASR 14775 animals were approximately 12 weeks old and weighed 25.4 to 52.0 kg at the start of the study. Trial-ASR 14820 animals were approximately 8 weeks old and weighed 11.4 to 22.4 kg at the start of the study.
 - b. Induced infection: Approximately 2500 infective larvae of *S. ransomi* were given by subcutaneous injection to each animal ten days before the start of treatment.
 - c. Dosage form and dose of test article: Type C medicated feed fed to provide 100 mcg ivermectin/kg body weight/day for 7 days. Controls animals received feed containing vehicle of the IVOMEC® Premix fed daily for 7 days.
 - d. Test duration and pertinent variables measured: Worm counts were determined at necropsy 14 days after start of treatment.
4. Results: Trial results are summarized in Tables 4.5.

Table 4.5. Mean worm counts and percent efficacy in growing pigs fed 100 mcg ivermectin/kg body weight/day for 7 days

Treatment Group	Adult <i>S. ransomi</i> ^a	Percent reduction
Trial ASR 14775		
Vehicle Control	869.3	-
IVOMEC® Premix	0	100
Trial ASR 14820		
Vehicle Control	2126.0	-
IVOMEC® Premix	3.0	>99

^aArithmetic mean

5. Conclusion: Under the conditions of this study, IVOMEC® Premix for Swine controlled infections of adult *Strongyloides ransomi*.

6. Adverse reactions: No adverse events related to treatments were observed.

B. Effectiveness of the top dress

Specific studies addressing the effectiveness of IVOMEC® Premix for Swine when used as a top dress intake were not required because 1) the formulation of Type C feeds with respect to feed ingredients is not specified; 2) treated animals are not ill or otherwise demonstrating poor appetite; 3) the labeling states that the top dress is for individually-fed adult and breeding swine; and 4) with respect to the concentration of the drug, the Type C feed is palatable as demonstrated in non-pivotal palatability studies previously submitted to the parent application which included doses up to 6X of the high end of the allowable concentration of the Type C medicated feed.

V. ANIMAL SAFETY

Animal safety is discussed in FOI Summaries for NADA 140-974 dated September 23, 1993 (58 FR 58652; Nov. 3, 1993), and June 29, 1995 (60 FR 39847; Aug. 4, 1995).

VI. HUMAN SAFETY

Human food safety is discussed in FOI summaries for NADA 140-974 dated September 23, 1993 (58 FR 58652; Nov. 3, 1993), and June 29, 1995 (60 FR 39847; Aug. 4, 1995).

Based on a battery of toxicological studies, an Acceptable Daily Intake (ADI) of 1 mcg/kg body weight/day has been established for ivermectin. A tolerance of 20 ppb for residues of 22, 23-dihydroavermectin B1a (the marker residue) in liver (the target tissue) has been codified at 21 CFR 556.344. Concentrations of marker residue below the tolerance in the target tissue indicate that the total residues of the drug in all edible tissues are below their respective safe concentrations.

No additional residue studies were conducted for the top dress because the Agency concluded that, given the feeding practices for sows, there would be no significant difference in tissue residue levels of ivermectin at the prescribed withdrawal period (5 days) resulting from feeding via a top dress as compared to feeding in a complete feed. Data summarized in Sections 6.C and 6.D of the September 23, 1993, FOI Summary for this NADA support this conclusion.

As part of the approval of this supplement, the Agency has taken the opportunity to update the human food safety information on this product and codify the Acceptable Daily Intake (ADI) of 1 mcg/kg body weight/day and a muscle tolerance of 20 ppb for residues of 22, 23-dihydro-avermectin B1a. Residues of 22, 23-dihydro-avermectin B1a below 20 ppb in muscle indicate that total residues of the drug in muscle are below the muscle safe concentration. Muscle residues of drug at or below the muscle tolerance are not indicative of the safety of other edible tissues in swine for human consumption.

VII. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA satisfy the requirements of section 512 of the Act and demonstrate that IVOMEC® Premix for Swine when used under the proposed conditions of use, is safe and effective for treatment and control of threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, *via* the colostrum or milk, when fed during gestation). No additional data was required for the use of Type C medicated feed as a top dress for adult swine due to data contained in the parent application.

The preslaughter withdrawal period following 7 consecutive days of feeding ivermectin to swine at a level of 0.1 mg/kg body weight per day remains at 5 days. As described in Section VI., a muscle tolerance of 20 ppb is established for residues of 22, 23-dihydro-avermectin B1a.

Adequate directions for use have been written for the layman, and the conditions for use prescribed on the labeling are likely to be followed in practice. Therefore, the Center for Veterinary Medicine (CVM) has concluded that this product shall retain over-the-counter marketing status.

In accordance with 21 CFR 514.106(b)(2)(v), this is a Category II change. The approval of this change did not require a reevaluation of the safety or effectiveness data in the parent application.

This action qualifies for a categorical exclusion from the requirement to prepare an environmental assessment under 21 CFR 25.33(a)(1) and (7).

Under section 512 (c)(2)(F)(iii) of the FFDCFA, this approval for food producing animals qualifies for THREE (3) years of marketing exclusivity beginning on the date of approval because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. The THREE years of marketing exclusivity only applies to the claim for treatment and control of threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, *via* the colostrum or milk, when fed during gestation).

VIII. APPROVED PRODUCT LABELING (attached)

- A. Facsimile labeling for IVOMEC® Premix for swine,
Type A medicated article, 0.6%, 50# bag (22.68 kg)
- B. Bluebird labeling for Type B medicated feed
Ivermectin at 18.2-1180 g/ton
- C. Bluebird labeling for Type C medicated feed
Ivermectin at 1.8 g/ton for Weaned, Growing, and Finishing Pigs
Ivermectin at 1.8-11.8 g/ton for Adult and Breeding Swine
Ivermectin at 18.2-1180 g/ton for Top Dress Use for Adult and Breeding Swine

Product 41284

Ivomec®

(ivermectin)

Premix for Swine

Type A Medicated Article

Antiparasitic



ACTIVE DRUG INGREDIENT

Ivermectin . . . 0.6%

INGREDIENTS

Ground Corn Cob

SEE DIRECTIONS ON BACK PANEL

TO BE USED ONLY IN THE MANUFACTURE OF SWINE FEEDS

Important: Must be diluted in feed before use

Merial Limited

2100 Ronson Road

Iselin, New Jersey 08830-3077, U.S.A.

MADE IN THE NETHERLANDS

28072/141093

8843301F

**Net Wt 50 lb
(22.68 kg)**



IVOMEC[®] Premix for Swine (ivermectin) Type A Medicated Article

Product 41284

INDICATIONS

For the treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrogylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae), kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae), lungworms (*Metastrongylus* spp., adults), threadworms (*Strongyloides ransomi*,

adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via colostrum or milk, when fed during gestation), lice (*Haematopinus suis*) and mange mites (*Sarcoptes scabiei* var. *suis*) when incorporated into complete swine feeds at the level listed in the tables below. Follow mixing directions when preparing complete feeds.

DOSAGE AND ADMINISTRATION

MIXING AND FEEDING DIRECTIONS FOR WEANED/GROWING/FINISHING PIGS:

Add IVOMEC Premix (Type A Medicated Article) to starter, grower and finisher feeds at 300 g per ton to supply 1.8 g ivermectin per ton (2 ppm) of feed.

Use this Type C Medicated Feed as the only feed *ad libitum* for 7 consecutive days. This provides approximately 0.1 mg ivermectin per kg (2.2 lb) of body weight per day.

MIXING AND FEEDING DIRECTIONS FOR ADULT AND BREEDING ANIMALS:

The recommended dose level for breeding animals is 0.1 mg ivermectin/kg body weight daily for seven consecutive days. Add IVOMEC Premix (Type A Medicated Article) to complete feed at 1.5 kg (3.3 lb) per ton to supply 9.1 g ivermectin per ton (10 ppm) of feed. Feed this Type C Medicated Feed at the rate of 1 lb (454 g) per 100 lb of body

weight daily for seven consecutive days. On a daily basis, any additional non-medicated feed should not be given until the medicated feed is consumed. For heavy animals being fed less than 1% of their body weight per day, the ivermectin level in the Type C Medicated Feed can be up to 11.8 g per ton.

As sow feeding practices vary during the different phases of their reproductive cycle (i.e., limited feeding during gestation and *ad libitum* during lactation), the inclusion rate of ivermectin per ton of complete feed can be adjusted accordingly to obtain the 0.1 mg/kg treatment level.

As an example, the following inclusion rates for IVOMEC Premix w/w (Type A Medicated Article) based on body weight and feed intake are determined by the formula.

$$\frac{\text{average body weight (lb)}}{\text{average daily intake (lb) per head} \times 30} = \text{lb of IVOMEC Premix (Type A Medicated Article) per ton of feed}$$

Average Body Weight (lb)	Daily Feed Intake (lb)	Premix (0.6%) per ton Type C Feed (lb)	Ivermectin Level in Type C Feed (g/ton)
400	4.0	3.33	9.1
	5.0	2.67	7.3
	6.0	2.22	6.1
500	4.0	4.17	11.3
	5.0	3.33	9.1
	6.0	2.78	7.8

IVOMEC Premix (Type A Medicated Article) should be thoroughly and evenly mixed in the feed in accordance with good manufacturing practices for medicated feeds.

Dispersion of IVOMEC Premix in the feed is enhanced by diluting 1 part of this 0.6% Type A Medicated Article with 14 parts of finely ground feed ingredients to provide an intermediate premix.

WARNING: WITHDRAW 5 days before slaughter.

Keep this and all drugs out of the reach of children.

CAUTION: • This product contains IVOMEC brand ivermectin and has been formulated specifically for use in swine only. This product should not be used for other animal species.
• Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

ENVIRONMENTAL SAFETY

Studies show that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish and certain water-borne organisms on which they feed. Do not permit water runoff from swine production sites to directly enter lakes, streams or ponds. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

IVOMEC and Pig Head logo are registered trademarks of Merial Limited.

U.S. PAT. 4,199,569

(Merial Limited: Registered in England and Wales [Reg. No. 3332751] with registered offices at 27 Knightsbridge, London, SW1X7QT, England and domesticated in Delaware, USA as Merial LLC).



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RECOMMENDED TREATMENT PROGRAM:

Weaned/Growing/Finishing Pigs:

All weaners/feeder pigs should be treated upon placement in clean quarters. Frequency of and need for additional treatments are dependent upon parasite exposure.

Adult and Breeding Animals: At the time of initiating any parasite control program, it is important to treat all animals in the herd. After the initial treatment, use IVOMEC Premix regularly as follows:

Sows: Treat, preferably, 14-21 days prior to farrowing to minimize parasitism of piglets.

Gilts: Treat, preferably, 14-21 days prior to breeding.

Boars: Treat, preferably, 14-21 days prior to farrowing.

Boars: Treat at least 2 times per year. Frequency of and need for additional treatments are dependent upon parasite exposure.

NOTE: (1) Since the effect of ivermectin on mange mites is not immediate, avoid contact between treated pigs and mange-free pigs for approximately one week after completion of treatment. Exposure of treated pigs to mange-infected pigs may result in reinfection.

(2) Louse eggs are unaffected by ivermectin and may require up to three weeks to hatch. Louse infestations developing from hatching eggs may require retreatment.

Lot & Exp Date

**BLUEBIRD
SWINE TYPE B MEDICATED FEED**

For the treatment and control of gastrointestinal roundworms (Ascaris suum, adults and fourth-stage larvae; Ascarops strongylina, adults; Hyoststrongylus rubidus, adults and fourth-stage larvae; Oesophagostomum spp., adults and fourth-stage larvae), kidneyworms (Stephanurus dentatus, adults and fourth-stage larvae), lungworms (Metastrongylus spp., adults), threadworms (Strongyloides ransomi, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation), lice (Haematopinus suis) and mange mites (Sarcoptes scabiei var. suis).

ACTIVE DRUG INGREDIENTS

Ivermectin18.2-1180 g/ton

GUARANTEED ANALYSIS

Crude Protein, not less than%
Crude Fat, not less than%
Crude Fiber, not more than%

INGREDIENTS

Each ingredient must be specifically named (unless stated as such in the guaranteed analysis listing) in accordance with the names and definitions adopted by AAFCO. Collective terms as listed in 21CFR§501.110 may be used where applicable.

MIXING DIRECTIONS

Mix 3.05 to 200 lb of this Type B Medicated Feed with feed ingredients (or unmedicated feed) to manufacture a Type C Medicated Feed containing 1.8 to 11.8 grams of ivermectin per ton.

DIRECTIONS FOR USE

- (1) Weaned, Growing & Finishing Pigs. Feed Type C Medicated Feed containing 1.8 g ivermectin/ton daily as the only feed for 7 consecutive days. This provides approximately 0.1 mg ivermectin per kg (2.2 lb) of body weight per day.
- (2) Adult & Breeding Animals: Feed the Type C Medicated Feed containing 1.8 to 11.8 g ivermectin/ton at a rate to deliver 0.1 mg ivermectin per kg (2.2 lb) of body weight per day for 7 consecutive days. Any additional feed should not be given until the daily medicated feed is consumed.

WARNING: **WITHDRAW 5 days before slaughter.**
Keep this and all drugs out of the reach of children.

CAUTION: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

This product contains IVOMEC brand ivermectin and has been formulated specifically for use in swine only. This product should not be used for other animal species. Do not permit water runoff from swine production sites to directly enter lakes, streams, or ponds. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

IVOMEC is a registered trademark of Merial Limited

Manufactured by

BLUEBIRD FEED COMPANY
City, State Zip Code

Net Weight on bag

BULK ONLY - OWN USE, NOT FOR SALE OR DISTRIBUTION**BLUEBIRD
SWINE TYPE B MEDICATED FEED**

For the treatment and control of gastrointestinal roundworms (Ascaris suum, adults and fourth-stage larvae; Ascarops strongylina, adults; Hyoststrongylus rubidus, adults and fourth-stage larvae; Oesophagostomum spp., adults and fourth-stage larvae), kidneyworms (Stephanurus dentatus, adults and fourth-stage larvae), lungworms (Metastrongylus spp., adults), threadworms (Strongyloides ransomi, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation), lice (Haematopinus suis) and mange mites (Sarcoptes scabiei var. suis).

ACTIVE DRUG INGREDIENTS

Ivermectin18.2-1180 g/ton

INGREDIENTS

Each ingredient must be specifically named (unless stated as such in the guaranteed analysis listing) in accordance with the names and definitions adopted by AAFCO. Collective terms as listed in 21CFR§501.110 may be used where applicable.

MIXING DIRECTIONS

Mix 3.05 to 200 lb of this Type B Medicated Feed with feed ingredients (or unmedicated feed) to manufacture a Type C Medicated Feed containing 1.8 to 11.8 grams of ivermectin per ton.

DIRECTIONS FOR USE

- (1) Weaned, Growing & Finishing Pigs. Feed Type C Medicated Feed containing 1.8 g ivermectin/ton daily as the only feed for 7 consecutive days. This provides approximately 0.1 mg ivermectin per kg (2.2 lb) of body weight per day.
- (2) Adult & Breeding Animals: Feed the Type C Medicated Feed containing 1.8 to 11.8 g ivermectin/ton at a rate to deliver 0.1 mg ivermectin per kg (2.2 lb) of body weight per day for 7 consecutive days. Any additional feed should not be given until the daily medicated feed is consumed.

WARNING: **WITHDRAW 5 days before slaughter.**
Keep this and all drugs out of the reach of children.

CAUTION: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

This product contains IVOMECC brand ivermectin and has been formulated specifically for use in swine only. This product should not be used for other animal species. Do not permit water runoff from swine production sites to directly enter lakes, streams, or ponds. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

IVOMECC is a registered trademark of Merial Limited

Manufactured by

BLUEBIRD FEED COMPANY
City, State Zip Code

Net Weight on bag

BLUEBIRD

TYPE C MEDICATED FEED
FOR WEANED, GROWING & FINISHING PIGS

For the treatment and control of gastrointestinal roundworms (Ascaris suum, adults and fourth-stage larvae; Ascarops strongylina, adults; Hyostrongylus rubidus, adults and fourth-stage larvae; Oesophagostomum spp., adults and fourth-stage larvae), kidneyworms (Stephanurus dentatus, adults and fourth-stage larvae), lungworms (Metastrongylus spp., adults), threadworms (Strongyloides ransomi, adults and somatic larvae), lice (Haematopinus suis) and mange mites (Sarcoptes scabiei var. suis).

ACTIVE DRUG INGREDIENTS

Ivermectin 1.8 g/ton

GUARANTEED ANALYSIS

Crude Protein, not less than	%
Crude Fat, not less than	%
Crude Fiber, not more than	%

INGREDIENTS

Each ingredient must be specifically named (unless stated as such in the guaranteed analysis listing) in accordance with the names and definitions adopted by AAFCO. Collective terms as listed in 21CFR§501.110 may be used where applicable.

FEEDING DIRECTIONS

Feed as the only feed daily for 7 consecutive days.

WARNING: **WITHDRAW 5 days before slaughter.**
 Keep this and all drugs out of the reach of children.

CAUTION: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

This product contains IVOMEK brand ivermectin and has been formulated specifically for use in swine only. This product should not be used for other animal species. Do not permit water runoff from swine production sites to directly enter lakes, streams, or ponds. Do not contaminate water by direct application or by the improper disposal of drug containers.

IVOMEK is a registered trademark of Merial Limited

Manufactured by

BLUEBIRD FEED COMPANY
City, State Zip Code

Net Weight on bag

BULK ONLY - OWN USE, NOT FOR SALE OR DISTRIBUTION**BLUEBIRD****TYPE C MEDICATED FEED
FOR WEANED, GROWING & FINISHING PIGS**

For the treatment and control of gastrointestinal roundworms (Ascaris suum, adults and fourth-stage larvae; Ascarops strongylina, adults; Hyostrongylus rubidus, adults and fourth-stage larvae; Oesophagostomum spp., adults and fourth-stage larvae), kidneyworms (Stephanurus dentatus, adults and fourth-stage larvae), lungworms (Metastrongylus spp., adults), threadworms (Strongyloides ransomi, adults and somatic larvae), lice (Haematopinus suis) and mange mites (Sarcoptes scabiei var. suis).

ACTIVE DRUG INGREDIENTS

Ivermectin 1.8 g/ton

INGREDIENTS

Each ingredient must be specifically named (unless stated as such in the guaranteed analysis listing) in accordance with the names and definitions adopted by AAFCO. Collective terms as listed in 21CFR§501.110 may be used where applicable.

FEEDING DIRECTIONS

Feed as the only feed daily for 7 consecutive days.

WARNING: **WITHDRAW 5 days before slaughter.**
 Keep this and all drugs out of the reach of children.

CAUTION: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

This product contains IVOMEK brand ivermectin and has been formulated specifically for use in swine only. This product should not be used for other animal species. Do not permit water runoff from swine production sites to directly enter lakes, streams, or ponds. Do not contaminate water by direct application or by the improper disposal of drug containers.

IVOMEK is a registered trademark of Merial Limited

Manufactured by

BLUEBIRD FEED COMPANY

City, State Zip Code

Net Weight on bag

BLUEBIRD

TYPE C MEDICATED FEED
FOR ADULT AND BREEDING SWINE

For the treatment and control of gastrointestinal roundworms (Ascaris suum, adults and fourth-stage larvae; Ascarops strongylina, adults; Hyostrongylus rubidus, adults and fourth-stage larvae; Oesophagostomum spp., adults and fourth-stage larvae), kidneyworms (Stephanurus dentatus, adults and fourth-stage larvae), lungworms (Metastrongylus spp., adults), threadworms (Strongyloides ransomi, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation), lice (Haematopinus suis) and mange mites (Sarcoptes scabiei var. suis).

ACTIVE DRUG INGREDIENTS

Ivermectin 1.8-11.8 g/ton

GUARANTEED ANALYSIS

Crude Protein, not less than	%
Crude Fat, not less than	%
Crude Fiber, not more than	%

INGREDIENTS

Each ingredient must be specifically named (unless stated as such in the guaranteed analysis listing) in accordance with the names and definitions adopted by AAFCO. Collective terms as listed in 21CFR§501.110 may be used where applicable.

FEEDING DIRECTIONS

Feed Type C Medicated Feed for 7 consecutive days at a rate to deliver 0.1 mg ivermectin per kg (2.2 lb) of body weight per day. Any additional feed should not be given until the daily medicated feed is consumed. As feeding practices for adult and breeding animals vary, this feed should be fed at an average of _____ lb per head per day for 7 consecutive days to animals of _____ lb average body weight.

WARNING: **WITHDRAW 5 days before slaughter.**
 Keep this and all drugs out of the reach of children.

CAUTION: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

This product contains IVOMEC brand ivermectin and has been formulated specifically for use in swine only. This product should not be used for other animal species. Do not permit water runoff from swine production sites to directly enter lakes, streams, or ponds. Do not contaminate water by direct application or by the improper disposal of drug containers.

IVOMEC is a registered trademark of Merial Limited

Manufactured by

BLUEBIRD FEED COMPANY
City, State Zip Code

Net Weight on bag

BULK ONLY - OWN USE, NOT FOR SALE OR DISTRIBUTION**BLUEBIRD****TYPE C MEDICATED FEED
FOR ADULT AND BREEDING SWINE**

For the treatment and control of gastrointestinal roundworms (Ascaris suum, adults and fourth-stage larvae; Ascarops strongylina, adults; Hyostrongylus rubidus, adults and fourth-stage larvae; Oesophagostomum spp., adults and fourth-stage larvae), kidneyworms (Stephanurus dentatus, adults and fourth-stage larvae), lungworms (Metastrongylus spp., adults), threadworms (Strongyloides ransomi, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation), lice (Haematopinus suis) and mange mites (Sarcoptes scabiei var. suis).

ACTIVE DRUG INGREDIENTS

Ivermectin 1.8-11.8 g/ton

INGREDIENTS

Each ingredient must be specifically named (unless stated as such in the guaranteed analysis listing) in accordance with the names and definitions adopted by AAFCO. Collective terms as listed in 21CFR§501.110 may be used where applicable.

FEEDING DIRECTIONS

Feed Type C Medicated Feed for 7 consecutive days at a rate to deliver 0.1 mg ivermectin per kg (2.2 lb) of body weight per day. Any additional feed should not be given until the daily medicated feed is consumed. As feeding practices for adult and breeding animals vary, this feed should be fed at an average of _____ lb per head per day for 7 consecutive days to animals of _____ lb average body weight.

WARNING: **WITHDRAW 5 days before slaughter.**
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ACTIVE DRUG INGREDIENTS

Ivermectin18.2-1180 g/ton

GUARANTEED ANALYSIS

Crude Protein, not less than	%
Crude Fat, not less than	%
Crude Fiber, not more than	%

INGREDIENTS

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DIRECTIONS FOR TOP DRESS USE

Adult & Breeding Animals: For individual treatment of gilts, pregnant sows and boars, add the appropriate amount of Type C Medicated Feed on top of the usual daily ration of each animal each day for seven consecutive days to achieve a total daily intake of 0.1 mg ivermectin per kg of body weight (4.54 mg ivermectin per 100 lb BW).

Note to the Feed Manufacturer: IVOMEC Premix for Swine Type C Medicated Feed for top dressing should be formulated and packaged so that the user is provided a measuring scoop, or other container, calibrated with markings to coincide with dosing directions. A table listing dosing directions should be included on the label and contain animal body weight, the number of scoops, or fractions thereof, to be top dressed, and the weight of Type C Medicated Feed in ounces or grams. This table on the Type C Medicated Feed label should provide dosing directions minimally for 100 lb increments of adult and breeding swine body weight. The label should indicate to use the scoop (container) specifically provided for top dressing that Type C Medicated Feed.

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TYPE C MEDICATED FEED
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Note: IVOMEC Premix for Swine Type C Medicated Feed for top dressing should be formulated so the user can calibrate a measuring scoop, or other container, with markings to coincide with dosing directions. A table listing dosing directions should be generated which contains animal body weight, the number of scoops, or fractions thereof, to be top dressed, and the weight of Type C Medicated Feed in ounces or grams. This table on the Type C Medicated Feed label should provide dosing directions minimally for 100 lb increments of adult and breeding swine body weight. The label should indicate to use the scoop (container) specifically provided for top dressing this Type C Medicated Feed.

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